UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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DOUGLAS J. HORN and CINDY HARP-HORN,

Civ Action No: 15-cv-701 FPG/MJR

Plaintiff,

-against-

AFFIDAVIT
PLAINTIFF'S EXPERT
DR. KENNETH GRAHAM

MEDICAL MARIJUANA, INC.,
DIXIE ELIXIRS AND EDIBLES,
RED DICE HOLDINGS, LLC, and
DIXIE BOTANICALS,

Defendants,

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STATE OF PENNSYLVANIA

COUNTY OF MONTGOMERY

BEFORE ME, the undersigned authority, personally appeared Kenneth D. Graham, Ph. D. who, after first being duly sworn, deposes and says:

1. My name is Kenneth D. Graham, Ph. D. I am a Forensic Toxicologist with over 25 years of experience in the field. My qualifications to render opinions in the field of forensic toxicology, pharmacology and labeling are fully set forth in my curriculum vitae, which is attached hereto as "Exhibit I" and incorporated herein by reference. I have personal knowledge of all matters contained in this affidavit.

2. I was retained on behalf of the Plaintiffs to evaluate the evidence and testimony involving the tetrahydrocannabinol (THC) content of Dixie X Elixir Tincture product taken by Plaintiff, and, specifically, the implications of using this product on a urine drug screen and whether the product complies with federal statutes for controlled substances.

3. In preparation for rendering my opinions, I reviewed the following case materials:

a. Statement of James Horn to Elizabeth Horn dated November 23, 2012.

b. Advertisement for Dixie X that appeared in the Fall 2012 Issue of High Times magazine.

c. Laboratory Litigation Package from Clinical Reference Laboratory related to a drug test analysis for specimen ID#2013672889 in October 2012.

d. Press release issued by Dixie Botanicals regarding product quality and efficacy clarification and dated November 26, 2013.

e. Email communications between James Horn and Scott Van Etten (EMSL Analytical, Inc.) dated November 8 and November 26, 2012.

f. Laboratory data and report for product testing order #281201415 issued by EMSL Analytical, Inc. on November 5, 2012.

g. FAQ webpage from Dixiex.com pulled on October 11, 2012.

h. Civil Complaint filed with the U.S. District Court, Western District of New York and dated August 5, 2015.

i. Follow-up SAP evaluation report prepared by Kenneth Dennis, Ph.D. on July 24, 2013.

j. Facebook post of Tamara Wise from November 20, 2013 and expose of Medical Marijuana, Inc. CBD products appearing on beyondTHC.com website.

k. Partial deposition transcript of James Horn dated May 8, 2017

l. CannLabs Certificate of Analysis for CBD 500 Dew Drop (or CBD0803MIXE2), Test ID: DED10.12.12-2 (PDF Files: 02475533xA984D; 02475534xA984D; 02475536xA984D).

m. CannLabs Certificate of Analysis: for CBD1011R&D-500 mg, Test ID: DED10.12.12-5 (PDF File: 02475535xA9B4D).

n. Report of Cindy S. Orser, Ph.D. dated September 29, 2017.

4. Appended as "Exhibit II" is my initial Report of August 29,2017 supporting my conclusions below.

5. Appended as "Exhibit III" is my October 30, 2017 Supplemental Report and Rebuttal to the defense's Botanical expert Dr. Cindy Orser.

6. Following my review of the aforementioned materials, I have concluded the following:

a. Defendants did not provide plaintiff, nor defendant's expert, process batch records, testing records or certificates of analyses pertaining to the actual product purchased and used by plaintiff. Failure to provide these documents suggests that either these records no longer exist or the formulation and product analyses were not conducted despite defendants advertising and statements that their products are rigorously tested multiple times during the manufacturing process using both traditional ISO17025 chemical testing facilities, as well as cannabinoid testing facilities, to ensure their products meet the highest standards.

b. The presence of at least 170 µg/g (170 ppm) of tetrahydrocannabinol (THC) measured by EMSL Analytical, Inc. (test date of November 5, 2012), in a Dixie X Elixir product containing a label quantity of 100 mg

cannabidiol (CBD) significantly exceeded by 3.4-fold the 50 ppm THC concentration in hemp products used in experimental studies that demonstrated the ability of such products to produce a positive THC drug screen result.

c. The results provided in certificates of analysis (CoA) prepared by CannLabs, Inc. (test date of October 16, 2012), for a labeled 500 mg Dixie X Dew Drop product contended to represent the similar product originally purchased and consumed by plaintiff indicates the product contained 500 µg/g (500 ppm) THC, which significantly exceeded by 10-fold the 50 ppm THC concentration in hemp products used in experimental studies that demonstrated the ability of such products to produce a positive THC drug screen result.

d. The use of Dixie X Elixir products also had the potential to yield additional THC exposure to consumers by conversion of CBD, the major ingredient in Dixie X Elixir, to THC in the acidic environment of the stomach as demonstrated by Watanabe and Itokawa, *et al.*, in Forensic Toxicology, 2007;25:16-21 and Merrick and Lane, *et al.*, in Cannabis and Cannabinoid Research, April 2016;1:102-112.

e. Based on the independent laboratory analysis requested by the plaintiff and the certificate of analysis records provided by defendants, Dixie X Elixir and similar Dixie products contained a measurable amount of THC. The Dixie X Elixir product was asserted to have "0%" THC and public statements by Dixie Elixirs and Edibles' managing director proclaimed the product "contains no THC". Defendant's content claims were contradicted

by the measurable presence of THC in the products and ostensibly represent false advertisement that would be unlawful under 15 U.S.C. §52. Based on these false claims, the plaintiff had his wife purchase the product believing that he could benefit from the wellness potential of the Dixie X Elixir derived from natural hemp without concern of it producing a positive THC drug test result under DOT drug testing guidelines that were applicable to his employment.

f. Since there was no evidence that indicated plaintiff had a history of either recreational or medicinal marijuana use, plaintiff's exposure to THC from his daily use of Dixie X Elixir for eight days preceding his DOT urine sample collection on October 9, 2012 was the direct cause of his positive THC drug test result that subsequently led to his loss of employment.

g. Dixie X Elixir was launched in early 2012 and was promoted as an imported industrial hemp-derived wellness product and CBD-rich medicine that contained either 100 mg or 500 mg of CBD and "0%" THC, suggesting that the product was free of tetrahydrocannabinol (THC), the most psychoactive constituent contributing to the behavioral effects and toxicity of cannabis. Industrial hemp strains are cultivated to increase the concentration of cannabidiol (CBD) and lower the concentration of THC content. Unlike THC, CBD is not psychoactive. In 2012, Federal law in the U.S. prohibited commercial farming of any variety of *Cannabis sativa*, but allowed for the importation and industrial use of hemp material if it maintained a THC content of less than 0.3% by weight. The 0.3% limit *does not apply to final product formulations* in which the presence of any

amount of THC would render it a Schedule 1 controlled substance as described under 21 U.S.C. §1308.11. Neither the defendants nor the defendant's expert provided a statute citation or other reference to support their contention that the Dixie Elixir products complied with Federal and state laws since the THC content in these products was below 0.3%. Despite a definition in many states of "CBD-only" products as having less than 0.3% or 0.5% THC, any product containing THC in any amount is considered marijuana and a Schedule I controlled drug substance under Federal law (21 U.S.C. §1308.11). Although Dixie X Elixir and similar Dixie products were derived from cannabis plant material (industrial hemp) that contained tetrahydrocannabinols, the products would not be eligible for an exemption to a Schedule I classification under 21 U.S.C. §1308.35 since the Dixie products were formulated, marketed and distributed for human consumption.

h. Despite recent decriminalization and compassionate medical use laws in some states, marijuana is not a benign drug and remains a Schedule I controlled substance under Federal law.

i. Since 170 µg/g (170 ppm) THC was measured by EMSL Analytical, Inc. in a Dixie X Elixir containing a labeled 100 mg CBD *and* 500 µg/g (500 ppm) THC was measured by CannLabs, Inc. in a Dixie X Dew Drop containing a labeled 500 mg CBD, these products and presumably similar representative Dixie products with differing lot numbers would be classified as Schedule 1 controlled substances under 21 U.S.C. §1308.11.

j. Dixie Elixir company website content and public statements issued by the managing director of Dixie Elixirs and Edibles denote that Dixie X Elixirs are tested multiple times during the manufacturing process using both ISO17025 compliant testing facilities as well as cannabinoid testing facilities. If the product was tested for cannabinoid content during the manufacturing process as claimed, then the results would have shown that Dixie X Elixir contained a measurable quantity of THC which would then classify the product as a DEA Schedule 1 substance under 21 U.S.C. §1308.35. Manufacturing process test results showing the presence of THC in the Dixie X formulation would signify that the advertising and public statements asserting the product contained no THC were false and may be unlawful under 15 U.S.C §52. Alternatively, if the formulation was not tested for cannabinoid content contrary to Dixie claims, the defendants would lack the knowledge to contend that their product contained no THC.

k. As neither the defendants nor the plaintiff were registered with the US Drug Enforcement Administration, the distribution of a Schedule I substance, such as Dixie X Elixir, across state lines would be apparently unlawful under 21 U.S.C §801-971 and, if the product was shipped through the domestic mail system, the distribution would also seemingly be unlawful under 18 U.S.C. §1716. In addition, the defendants manufactured and distributed a controlled substance in violation of 21 U.S.C. §841.

l. As a Schedule I controlled drug substance under 21 U.S.C. §1308.35, Dixie X Elixir was subject to specific packaging and labelling requirements under 21 U.S.C. §1302.03. Consequently, each commercial container of a controlled substance must contain a label providing definitive information of product contents and bearing the symbol designating the schedule on which the controlled substance is listed. The product label of the Dixie X Elixir used by the plaintiff did not list THC as an ingredient and did not bear a symbol reflecting that it was a Schedule I controlled substance and, therefore, violated packaging and labeling requirements under 21 U.S.C. §1302.03. Without the required label content, the plaintiff would not have been able to make an informed decision about whether to use the Dixie X Elixir product.

m. Since the manufacture and distribution of Dixie X Elixir appears to be unlawful under multiple Federal statutes, the advertising and public statement claims that the Dixie X Elixirs do not conflict with any Federal law and that the parent company, Medical Marijuana, Inc. does not grow, sell or distribute any substances that violate United States Law or the controlled substances act are false and appear to violate 15 U.S.C §52 covering the dissemination of false advertisement.

Dated: August 29, 2018

KENNETH D. GRAHAM, Ph.D., R.Ph.

Subscribed and Sworn to before me this
29 day of August, 2018.

Notary Public

Commonwealth of Pennsylvania - Notary Seal
Linda Connor, Notary Public
Montgomery County
My Commission Expires October 27, 2021
Commission number 1219910